

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Sidney Smith et al.
Appl. No.: 09/813,351
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Title: LARGE VOLUME FLEXIBLE CONTAINER
Art Unit: 3727
Examiner: Jes F. Pascua
Docket No.: CRTS-5679 (0112713-968)

Assistant Commissioner of Patents
Washington, D.C. 20231

AFFIDAVIT OF SIDNEY T. SMITH UNDER 37 C.F.R. § 1.132

Sir:

I, Sidney T. Smith, hereby state as follows:

1. My education is as follows: I have a Bachelor of Science degree in Chemistry and have completed graduate coursework in Chemical and Biomedical Engineering and Biophysical Chemistry. My work experience includes over 20 years in the design and development of flexible container technology for medical applications, biopharmaceutical solutions, and the biosciences. In addition, I have presented numerous articles on flexible barrier container technology at several industry symposiums.

2. I am one of the named inventors of the above-identified patent application and I am therefore familiar with the inventions disclosed therein. I have recently reviewed the claims of the patent application as they are currently pending. A copy of the pending claims is attached hereto at Tab A.

3. One of the problems with conventional flexible containers for containing large volumes of bio-pharmaceutical solutions of at least 200 liters is that hydraulic forces such as fluid stress and shear that occur within the container, particularly during container transport, are significant enough to rupture the container seams. The present invention is directed to a large

volume flexible container with an improved end panel design that significantly strengthens the container making it more resistant to rupture. Accordingly, in part, the claimed invention provides a large volume flexible container having end segments wherein the angle between the tapered edge of the end segment and the panel peripheral edge is between 135.01° to 138° . This angle range enables the container end panels to extend beyond the plane formed by the sleeve ends. This extended end panel configuration enables the hydraulic stress imposed upon the filled flexible container to be transferred to a support container in which the flexible container is placed.

4. Through a series of experiments, I surprisingly and unexpectedly discovered that by forming an angle of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge, I was able to produce a wrinkle-free large volume flexible container with improved strength and improved resistance to rupture. Providing an angle between 135.01° and 138° permits the end panels to extend outwardly beyond the plane defined by the panel sleeve ends when the container is filled. The outwardly extending end panel, or the "pent roof" feature of the container, provides additional material at the end panel apex forming a flexible container with a wetted surface area that equals or exceeds the wetted surface area of the support container. The outwardly extending end panel thereby reduces the amount of hydraulic stress placed upon the filled container by allowing the hydraulic stress to be transferred to the support container. The angle range of 135.01° to 138° further unexpectedly provides a flexible container that does not wrinkle when placed into the support container.

5. When I prepared large volume flexible containers having an angle less than 135.01° , the end panels did not extend beyond the plane formed by the panel sleeve ends. Consequently, the flexible containers carried excessive stress in the seams and could not transfer the stress to the support container. These flexible containers were prone to rupture. The containers I prepared having an angle greater than 138° exhibited wrinkling when placed in the support container. Wrinkling is deleterious as it prevents proper filling and drainage of the fluid contents into and from the flexible container. As a result of my research and experimentation, I have discovered that the angle range of 135.01° to 138° between the tapered edge of the end segment and the panel peripheral edge produces containers for holding at least 200 liters of fluid

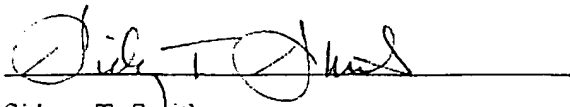
with the unexpected advantages of i) rupture resistant end panels and ii) wrinkle-free filling and draining.

6. A reference relied upon by the Patent Office is U.S. Patent No. 5,988,422 to Vallot (*Vallot*). *Vallot* discloses a parallelepiped-shaped sachet for transporting biopharmaceutical liquids. The end panels of the *Vallot* container are formed by cutting the edges of the film at a $45^\circ \pm 15^\circ$ angle relative to the vertical axis of the sachet. This translates to an angle range of 120° - 150° between the panel peripheral edge and the end segment tapered edge. *Vallot*, however, does not provide a single example of a container wherein the angle is greater than 45° . Conversely, *Vallot* states that the welds on the bottom face and the top face of the parallelepiped sachet are parallel. This clearly indicates that the angle is exactly 45° .

7. Moreover, *Vallot* provides no disclosure regarding a container with end panels that extend beyond the plane defined by the panel ends. Provision of a parallelepiped container requires the *Vallot* end panels to be coplanar with the plane defined by the panel ends. Accordingly, *Vallot*'s end panels do not extend beyond the plane defined by the panel ends. In addition, *Vallot* discloses that the flexible container "conforms exactly to the geometry" (col. 5 lines 53-56) of the support container in which it is placed. This further demonstrates that the end panels of the *Vallot* container do not extend beyond the plane defined by the panel ends and further indicates that the angle of the *Vallot* container is not greater than 45° . Regardless of the disclosure of an angle range of $45^\circ \pm 15^\circ$, it is apparent that *Vallot* fails to recognize the need to transfer stress from the flexible container to the support container and subsequently fails to provide a solution to this need. *Vallot* simply discloses a parallelepiped container wherein the angle between the panel peripheral edge and the end segment tapered edge is exactly 135° . As one skilled in the art reviewing *Vallot*, I would not be taught nor would I be led to construct a large volume flexible container with an end panel that outwardly extends beyond the plane defined by the fold line of each panel. Nor would I be led to construct a large volume flexible container with the angle range of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge that permits stresses on the filled flexible container to be transferred to the support container and reinforcing the end panels while simultaneously providing a flexible container that does not wrinkle during filling and draining.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from this application.

FURTHER AFFIANT SAYETH NOT:


Sidney T. Smith

7 MARCH 2005
Date

Listing of Claims:

Claim 1 (canceled)

Claim 2 (previously presented): The container of claim 17 wherein the panels form a polygonal sleeve.

Claims 3-5 (canceled)

Claim 6 (previously presented): The container of claim 17 wherein the plurality of panels comprises four panels cooperatively forming a sleeve having a generally rectangular cross-section.

Claim 7 (original): The container of claim 6 wherein two opposing panels are gusseted panels.

Claim 8 (original): The container of claim 7 wherein the gusseted panels have a gusset fold.

Claims 9-11 (canceled)

Claim 12 (previously presented): The container of claim 17 wherein the end segments converge to a line.

Claim 13 (canceled)

Claim 14 (previously presented): The container of claim 17 wherein one of the panels has a port.

Claim 15 (previously presented): The container of claim 14 wherein the port has a port closure in sterile communication with the port, the port closure providing sterile access to the container interior.

Claim 16 (canceled)

Claim 17 (currently amended): A flexible container composed of a polymeric material for holding at least 200L of fluid comprising:

a plurality of panels, each panel having a peripheral edge, an end, and an end segment extending from the end, the end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the plurality of panels joined together along the peripheral edges to form a sleeve, the panels each having a fold line that cooperate to define an imaginary plane at one end of the sleeve;

an end panel composed of the plurality of end segments folded at the fold line and sealed to each other along the tapered peripheral edges, at least one angle having a range from 135.01° to about 138° and forming at least one end segment with an additional amount of material which permits at least a portion of the end panel to extend outwardly from the sleeve beyond the imaginary plane when the first end panel is in an unfolded position; and

a second end panel formed at another end of the sleeve to form a closed flexible container.

Claim 18 (previously presented): The container of claim 17 wherein the panels each have a second end and a second end segment extending from each second end, each second end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the panels each having a second fold line that cooperate to define a second imaginary plane at the second end of the sleeve, the second end panel composed of the plurality of the second end segments; folded at the fold line and sealed to each other along the tapered peripheral edges, at least a second angle having a range from 135.01° to about 138° and forming at least one second end segment with an additional amount of material which permits at least a portion of the second end panel to extend outwardly from the sleeve beyond the second imaginary plane.

Claim 19 (previously presented): The container of claim 17 further comprising first and second opposing side panels wherein the first and second opposing panels are folded on top of themselves when the flexible container is in a folded position.

Claim 20-21 (canceled)

Claim 22 (previously presented): The container of claim 17 wherein the at least one angle is in the range from about 135.5° to about 136.5°.

Claim 23 (previously presented): The container of claim 17 wherein the at least one angle is 136°.

Claim 24-28 (canceled)

Claim 29 (previously presented): The flexible container of claim 17, further comprising a plurality of spaced-apart hanger connection locations at a top side of the flexible container, the hanger connection locations positioned inward from an outer edge of the top side.

Claim 30 (previously presented): The flexible container of claim 17, wherein the end panel extending outwardly beyond the imaginary plane is a bottom side of the flexible container.

Claim 31 (previously presented): The flexible container of claim 17, wherein the first end panel extending outwardly beyond the imaginary plane has a generally vertical orientation.

Claims 32-35 (canceled)

Claim 36 (previously presented): The container of claim 15 wherein the port closure further comprises a communication member having an end attached to the port.

Claim 37 (previously presented): The container of claim 36 wherein the communication member has a length of about six feet to about 30 feet.

Claim 38 (previously presented): The container of claim 36 further comprising a stop member attached to a second end of the communication member.

Claim 39 (previously presented): The container of claim 38 wherein the stop member is a gas permeable, sterile barrier.

Claim 40 (previously presented): The container of claim 39 wherein the barrier prevents fluid from passing into the communication member.

Claim 41 (previously presented): The container of claim 38 further comprising a cover member.

Claim 42 (previously presented): The container of claim 41 wherein the cover member covers the stop member and a portion of the second end of the communication member.

Claim 43 (previously presented): The container of claim 15 further comprising a second port and a vent closure in sterile communication with the second port.

Claim 44 (previously presented): The container of claim 43 wherein the vent closure further comprises a vent tube having an end attached to the second port.

Claim 45 (previously presented): The container of claim 44 wherein the vent closure further comprises a vent plug attached to a second end of the vent tube.

Claim 46 (previously presented): The container of claim 45 wherein the vent plug is a gas permeable sterile barrier to the vent tube.

Claim 47 (previously presented): The container of claim 46 wherein the vent plug equalizes the internal and external container pressure.

Claim 48 (previously presented): The container of claim 47 wherein the vent plug permits complete filling of the container.

Claim 49 (previously presented): The container of claim 48 further comprising a vent valve disposed within said vent tube.

Claim 50 (canceled)

Claim 51 (previously presented): The container of claim 17 further comprising a plurality of spaced-apart hanger connectors on a top panel of the plurality of panels, the hanger connectors being located between a center of the top panel and an outer perimeter edge of the top panel.

Claim 52 (previously presented): The container of claim 17 wherein the entire end panel extends beyond the imaginary plane.

Claim 53 (previously presented): The container of claim 18 wherein the entire second end panel extends beyond the second imaginary plane.

Claim 54 (previously presented): The container of claim 18 wherein each end segment has opposing tapered peripheral edges.

Claim 55 (previously presented): The container of claim 18 wherein the at least second angle is in the range from about 135.5° to about 136.5°.

Claim 56 (previously presented): The container of claim 18 wherein the at least second angle is 136°.